

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/)	
FENFLURAMINE/DEXFENFLURAMINE))	MDL NO. 1203
PRODUCTS LIABILITY LITIGATION)	
)	
THIS DOCUMENT RELATES TO:)	
)	
SHEILA BROWN, et al.)	CIVIL ACTION NO. 99-20593
v.)	
AMERICAN HOME PRODUCTS)	2:16 MD 1203
CORPORATION)	

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.

851

Bartle, C.J.

July 19, 2010

Joyce S. Roeser ("Ms. Roeser" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").²

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In February, 2003, claimant submitted a completed Green Form to the Trust signed by her attesting physician, John P. Orchard, M.D., F.A.C.C. Based on an echocardiogram dated November 10, 1996, Dr. Orchard attested in Part II of Ms. Roeser's Green Form that she suffered from severe mitral regurgitation and had surgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or

2. (...continued)

not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

Redux™.³ Based on such findings, claimant would be entitled to Matrix A-1, Level III benefits in the amount of \$719,285.⁴

In the report of claimant's echocardiogram, the reviewing cardiologist, Steven L. Benton, M.D., stated that "[e]valuation of the mitral valve indicates moderate, nonspecific anterior mitral leaflet thickening and probably normal posterior mitral leaflet thickness and excursion." Dr. Orchard, however, attested in claimant's Green Form that Ms. Roeser did not suffer from mitral annular calcification. Under the Settlement Agreement, the presence of mitral annular calcification requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)ii)d). As the Trust does not contest Ms. Roeser's entitlement to Level III benefits based on surgery to repair or replace her mitral valve, the only issue before us is whether claimant is entitled to payment on Matrix A-1 or Matrix B-1.

In October, 2003, the Trust forwarded the claim for review by M. Michele Penkala, M.D., one of its auditing cardiologists. In audit, Dr. Penkala concluded that there was no reasonable medical basis for Dr. Orchard's finding that claimant

3. Dr. Orchard also attested that claimant suffered from abnormal left ventricular end-systolic dimension and a reduced ejection fraction in the range of 35% to 39%. These conditions, however, are not at issue in this claim.

4. Under the Settlement Agreement, a claimant is entitled to Level III benefits if he or she suffers from "left sided valvular heart disease requiring ... [s]urgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™." See Settlement Agreement § IV.B.2.c.(3)(a).

did not have mitral annular calcification because "there appears to be mild mitral annular calcification involving both the anterior and posterior annulus." In addition, Dr. Penkala noted that:

The mitral valve is abnormal with nonspecific thickening as well as focal calcification of the anterior mitral valve leaflet. There is also what appears to be a redundant chord with some focal calcification to the anterior mitral valve leaflet and no definite evidence of prolapse. There is mild [mitral annular calcification].

Based on Dr. Penkala's finding that claimant had mitral annular calcification, the Trust issued a post-audit determination that Ms. Roeser was entitled only to Matrix B-1, Level III benefits.⁵ Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁶ In contest, claimant argued that a reasonable medical basis existed for Dr. Orchard's finding that claimant did not have mitral annular calcification. In support, claimant suggested that the auditing cardiologist's determination

5. The Trust's initial post-audit determination identified reduction factors not found by Dr. Penkala during audit. In response to claimant's contest of this determination, the Trust issued an amended post-audit determination consistent with Dr. Penkala's findings at audit.

6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Roeser's claim.

that "there appears to be mild [mitral annular calcification]" is insufficient to conclude that Dr. Orchard's representation was without a reasonable medical basis. In addition, claimant submitted letters from Dr. Orchard and Allen L. Dollar, M.D., F.A.C.P., F.A.C.C. Dr. Orchard stated that he re-reviewed Ms. Roeser's echocardiogram and found no evidence of mitral annular calcification. Similarly, Dr. Dollar opined that claimant did not have mitral annular calcification.

Specifically, Dr. Dollar stated:

The appearance of fibrotic, non-calcified tissue by echocardiogram is essentially indistinguishable from a small or mild amount of calcification. Thus, the finding of a 'mild' degree of mitral annular calcification is entirely a subjective one. Only when there is moderate or severe mitral annular calcification present can one be definitive about the presence of calcium.

I have reviewed this study several times on a frame-by-frame basis and I completely disagree with Dr. Penkala's finding of mitral annular calcification. Indeed, there isn't really any abnormal fibrotic tissue in the annulus. The anterior leaflet is mildly thickened without evidence of calcification. There is no shadowing below the annulus to suggest the presence of calcium deposits.⁷

The Trust then issued a final post-audit determination, again determining that Ms. Roeser was entitled only to

7. Claimant also argued that the Trust's amended post-audit determination was untimely and that her claim should, as a result, be paid. Ms. Roeser, however, failed to demonstrate how she was prejudiced by this delay. As we previously discussed in PTO No. 6339, "we are unwilling to order payment on an uncompensable claim solely based on an 'out of time' argument without, at a minimum, some showing of prejudice." PTO No. 6339 at 13 n.10 (May 25, 2006).

Matrix B-1, Level III benefits. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement.

See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Roeser's claim should be paid. On August 9, 2004, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 3817 (Aug. 9, 2004).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on November 24, 2004. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor⁸ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical

8. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she did not have mitral annular calcification. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Roeser reasserts the arguments made in contest; namely, that there is a reasonable medical basis for finding that she did not have mitral annular calcification. According to claimant, the auditing cardiologist's statement that there "appears" to be mitral annular calcification is insufficient to support the Trust's argument that Ms. Roeser had mitral annular calcification. In addition, claimant contends that the medical evidence contradicts Dr. Penkala's finding.

In response, the Trust argues that Dr. Penkala provided an adequate explanation for her finding that there was no reasonable medical basis for the attesting physician to state

that claimant did not have mitral annular calcification. The Trust also submits that the letter from claimant's expert, Dr. Dollar, does not establish a reasonable medical basis for the attesting physician's representation because it merely states Dr. Dollar's opinion rather than refutes Dr. Penkala's determination. Finally, the Trust asserts that claimant cannot meet her burden of proof simply by proffering opinions from additional physicians, such as Dr. Dollar.⁹

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that claimant did not have mitral annular calcification. Specifically, Dr. Vigilante stated, in pertinent part, that:

There is obvious mitral annular calcification noted both in the medial and posterolateral areas of the annulus. The calcification was more significant medially than posterolaterally. In both the parasternal long axis and short axis views, mitral annular calcification could be seen. There is also calcification of the mid portion of the body of the anterior mitral leaflet although this leaflet opened and closed adequately.... There was thickening and calcification of chords and one of the chords was ruptured. This ruptured chord was clearly calcified. The calcification of the mitral annulus also involved part of the aortic annulus. The apical four chamber and

9. The Trust also argues that under Rule 26(a)(2) of the Federal Rules of Civil Procedure, physicians who proffer opinions regarding claims must disclose their compensation for reviewing claims and provide a list of cases in which they have served as experts. We disagree. We previously have stated that Rule 26(a)(2) disclosures are not required under the Audit Rules. See PTO No. 6996 at 7 n.10 (Feb. 26, 2007).

apical two chamber views also demonstrated obvious mitral annular calcification with calcified ruptured chord and calcification of the anterior mitral leaflet.

* * *

[T]here is not a reasonable medical basis for the Attesting Physician's answer to Green Form [question] D.9. That is, mitral annular calcification is clearly noted on the echocardiographic study of November 10, 1996. This [mitral annular calcification] co-exists with calcification of the anterior mitral leaflet chords and tip of papillary muscle. It would be impossible for a reasonable echocardiographer to conclude that mitral annular calcification was not present on this study.

In response to the Technical Advisor Report, claimant argues that the Trust did not have an adequate basis for denying the claim, and that "reasonable physicians, including Dr. Dollar and Dr. Orchard, clearly disagree" with the Technical Advisor's conclusions.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, we disagree with claimant that Dr. Penkala did not adequately support her determination. To the contrary, Dr. Penkala specifically determined that claimant's "mitral valve is abnormal with nonspecific thickening as well as focal calcification of the anterior mitral valve leaflet.... There is mild [mitral annular calcification].." These statements by the auditing cardiologist are sufficient to support the Trust's post-audit determination.

We also reject claimant's argument that the opinions of Dr. Orchard and Dr. Dollar provide a reasonable medical basis for

Dr. Orchard's determination. In addition to Dr. Penkala's findings, the Technical Advisor, Dr. Vigilante, concluded that claimant's echocardiogram demonstrated "obvious mitral annular calcification" and that "[i]t would be impossible for a reasonable echocardiographer to conclude that mitral annular calcification was not present on this study."

Finally, we do not agree with Dr. Dollar that Dr. Penkala mistook fibrotic, non-calcified tissue for calcification. Despite an opportunity to do so, claimant did not rebut or refute Dr. Vigilante's specific finding that this is not the type of study where it is difficult to distinguish fibrotic, non-calcified tissue from a small amount of calcification.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she did not have mitral annular calcification. Therefore, we will affirm the Trust's denial of Ms. Roeser's claim for Matrix A-1 benefits.